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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,536	01/23/2002	Sukanta Dutta	1997.341 US D1	9200

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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,536	DUTTA ET AL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. The Restriction Requirement mailed 10/4/04 is rendered moot. A Preliminary Amendment was filed on January 23, 2002 which cancelled claims 1-27 and added new claims 28-35. The Restriction Requirement was directed to the former claims. The Preliminary Amendment has since been properly entered into the file. Claims 28-35 are directed to a single invention so no Restriction Requirement is being made.

Claims 28-35 are currently under examination.

Specification

2. The current status of all nonprovisional parent applications referenced should be updated on the first page of the specification, e.g., the US Patent No. of 09/157,257 should be added in the first paragraph.

3. The disclosure is objected to because of the following informalities:

The 'Brief Description of the Drawings' should be updated to include the correct reference of the figures, e.g., 'Figure 2' should be changed to 'Figure 2A-2C', etc. Figures 2-5 all need to be updated so they correspond correctly to the drawings.

Appropriate correction is required.

Drawings

4. The drawings are objected to because Figure 3 refers to 'Figure 3A and 3C'. However, it appears that 'Figure 3C' should be labeled 'Figure 3B' because there are only 2 pages of Figure 3 and the sequence appears to be in sequential order.

Appropriate correction is required.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84©) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Sequence Compliance

5. The instant specification also contains several nucleotide/amino acid sequences throughout the specification which are also encompassed by the definitions for nucleotide/amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) and which must conform with the sequence rules for all applications that include nucleotide/amino acid sequences. The sequence identifiers obtained through conformance (paper submission and CRF/electronic) must be inserted into the body of the specification directly following the sequence. Pages 34, lines 20 and 23-24; page

42, lines 18-19; page 43, lines 5, and 11-12, the Table on pages 47-49, etc. were found to contain sequences. Additionally, Applicants are responsible for meeting compliance with any sequence the Examiner may have inadvertently missed. It is noted that these sequence identifiers were added properly added during the prosecution of parent application 09/157,257. APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R. 1.821-25. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 28-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28 and 29 are vague and indefinite because it is unclear what is encompassed by a bacterial strain which has "essentially the same antigenic characteristics of *E.risticii* strain 90-12". What characteristics are these? Additionally, the language "essentially the same antigenic characteristics of *E.risticii* strain 90-12" cannot be found in the original disclosure. Claim 29 is even more vague because the

strain does not even have to be another *Erhlichia* strain, but can be any genus of bacterium with similar antigenic characteristics. 'Antigenic characteristics' can be broadly interpreted as the ability to raise antibodies. The claims are not adequately defined. Clarification and correction is requested.

Claim Rejections - 35 USC § 112-Written Description

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 28-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The originally filed specification and originally filed claims fail to provide written support for the subject matter recited in the newly submitted claims. The language 'An isolated strain of *E. risticii* having essentially the same antigenic characteristics of *E. risticii* strain 90-12' and 'An isolated strain of an organism having essentially the same antigenic characteristics of *E. risticii* strain 90-12' cannot be found in the instant specification. Additionally, the specification does not teach or recite vaccines comprising these strains or method of protecting a mammal against Potomac Horse Fever comprising administering these strains. The limitation "killed vaccine" in reference to the strains recited in claims 28 and 29 cannot be found anywhere in the

original specification or claims. The specification teaches isolated surface-expressed proteins from well-known *E. risticii* strains 90-12 and 25D and methods of detection and immunization using these isolated strains. However, there is no written description provided for an isolated *E.risticii* strain other than the 90-12 strain and 25D strain. The specification is silent with respect to killed whole cell vaccines and methods of protection using said killed whole cell vaccines. Written support is not found for the new claims.

The specification briefly recites "variant 90-12 strains of *E.risticii*", but it is unclear what these variant strains comprise. These strains should be deposited if they are newly discovered and cannot be shown to be reproducible. Additionally, for purposes of future amendment, the term "variant" is not sufficient to adequately describe the strains. The claim should provide any structural properties, deposits or mutation description (provided there is written support), which would allow for one to identify the variants without ambiguity.

Claim Rejections - 35 USC § 112-Enablement

10. Claims 28-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are broadly drawn to 'An isolated strain of *E. risticii* having essentially the same antigenic characteristics of *E. risticii* strain 90-12' and 'An isolated

strain of *any organism* having essentially the same antigenic characteristics of *E. risticii* strain 90-12'. Vaccines comprising these strains and method for protecting a mammal against Potomac Horse Fever using said vaccines are also claimed. However, the instant specification only describes *E.risticii* strain 90-12 (isolated in 1990) and *E.risticii* strain 25D (isolated in 1984). These strains were used to isolate strain specific surface antigens which the application teaches can be used in vaccines. The specification provides no description of any other *E.risticii* strains. There is no teaching of any other bacterial organism which has "essentially the same antigenic characteristics of *E. risticii* strain 90-12'. The specification does not provide written description or enablement for these other strains. Additionally, there is no description of using these strains in killed whole cell preparation for protecting a mammal against Potomac Horse Fever. The prior art teaches inactivated strains *E.risticii* strain 90-12 (isolated in 1990) and *E.risticii* strain 25D (isolated in 1984) were well known as whole cell vaccines. However, there is no description of any other strains in the prior art or instant specification which have "essentially the same antigenic characteristics of *E. risticii* strain 90-12' and can be successfully used as a vaccine. Additionally, the word "killed" (e.g., killed vaccine) cannot be found in the instant specification, nor can the limitation "essentially the same antigenic characteristics of *E. risticii* strain 90-12'. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting

license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." It would take one of skill in the art undue experimentation to discover a strain of a bacteria which has "essentially the same antigenic characteristics of *E. risticii* strain 90-12' and can successfully protect mammals against Potomac Horse Fever. The specification does not enable the instant claims.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Vemulapalli et al (J. Clin. Microbiol. Nov. 1995. 33(11): 2987-2993).

Vemulapalli et al teach isolated strains of *E.risticii* 90-12 and 25-D. These strains have "essentially the same antigenic characteristics of *E.risticii* 90-12". Vemulapalli et al also teach that strain variation in *E.risticii* is not unexpected because there are several different strains clearly established in other rickettsial organisms. Biological diversity of nine clinical isolates of *E.risticii* was reported in 1994. These nine other strains would

also have essentially the same antigenic characteristics of *E.risticii* 90-12". See page 2992, last paragraph, column 1. As stated in the 112, second paragraph rejection above, it is unclear what is encompassed by a strain which has 'essentially the same antigenic characteristics of *E.risticii* 90-12 . 'Antigenic characteristics' can be broadly interpreted as the ability to raise antibodies. The term "vaccine" which is recited in claims 30 and 31 is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The reference describes mouse protection experiments which comprise administering an effective amount of strains *E.risticii* 90-12 and 25-D to mice and then challenging them with the strains. Administration of strain *E.risticii* 90-12 was shown to induce immunity to both wild-type *E.risticii* 90-12 and *E.risticii* 25-D.

13. Claims 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Shankarappa et al. (Internat. J. Systematic Bacteriol. Jan. 1992. 42(1): 127-132).

Shankarappa et al disclose that *E.risticii* and *E.sennetsu* are serologically related, and their Western Blots were nearly identical. Accordingly, these strains have "essentially the same antigenic characteristics of *E.risticii* 90-12". The reference teaches isolated strains of both *E.risticii* and *E.sennetsu*. See abstract. . The term "vaccine" which is recited in claims 30 and 31 is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

14. Claims 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Dutta (US 4,759,927).

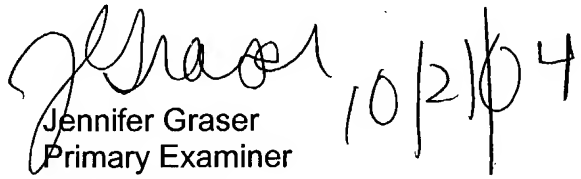
Dutta et al teach a vaccine against Potomac horse fever which comprises inactivated strains of *E.risticii.* The vaccine is chemically inactivated (killed). The vaccine was delivered to horse in a pharmaceutically acceptable carrier. The horses were subsequently challenged with *E.risticii.* The vaccine was shown to confer a large measure of protection. In many cases, no symptoms of Potomac horse fever were observed. See column 4, lines 38-67. The strain used by Dutta has "essentially the same antigenic characteristics of *E.risticii* 90-12". As stated in the 112, second paragraph rejection above, it is unclear what is encompassed by a strain which has 'essentially the same antigenic characteristics of *E.risticii* 90-12 . 'Antigenic characteristics' can be broadly interpreted as the ability to raise antibodies.

15. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.



Jennifer Graser
Primary Examiner
Art Unit 1645